

**K081916 GE SIGNA MR ONCOLOGY PACKAGE**Jul 22, 2008  
15 days to decisionK081916 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k081916/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 7, 2008
Decision date	Jul 22, 2008
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems, LLC</b>
Location	Waukesha, WI, US
Contact	Daniel Biank
Website	<a href="https://www.gehealthcare.com">https://www.gehealthcare.com</a>
510(k) history	104 submissions · 104 cleared · 2003-2026

GE Medical Systems, LLC is a medical device manufacturer based in Waukesha, US. The company specializes in Radiology devices and solutions. GE Medical Systems has received FDA 510(k) clearances from total submissions. The company's regulatory focus is entirely on Radiology devices, with a clearance history spanning from 2003 to 2026. The latest clearance in 2026 demonstrates active regulatory engagement within the past two years. Recent cleared devices include advanced imaging systems such as the Photonova Spectra series, SIGNA™ product line, AIR Recon DL, Revolution Vibe...

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